(2-propoxy-5-methanesulfonylamidophenyl)-1,5-dihydropyrazolo[3,4-d]pyrimidin-4-one in an atomisable composition or a finely divided particulate form.

28. (new) A medicament according to claim 27, in which the atomisable composition is an aerosol comprising said inhibitor in solution or dispersion in a propellant or a nebulizable composition comprising a dispersion of said inhibitor in an aqueous or aqueous/organic medium.

#3

29. (new) A medicament according to claim 27, in which said inhibitor in finely divided particulate form is inhaled together with a particulate carrier.

REMARKS

Claims 1-20 were pending in the instant application, all of which stand rejected. Applicant has cancelled claims 1-20 and replaced them with new claims 21-29. Support for new claims 20-29 can be found in, e.g., original claims 1, 2, 3, 4, 8, 11, 14, 17, and 20 respectively. It is submitted no new matter has been added by the instant amendment.

Applicant notes the acknowledgement of the claim for foreign priority but contrary to the indication that none of the copies of the priority documents have been received, applicant points out that the Claim for Priority and the priority document were sent with the Information Disclosure Statement (IDS), filed on September 18, 2001. Copies of the IDS, the priority document and the return postcard, indicating receipt by the PTO, are being sent herewith.

Applicant respectfully requests reconsideration and allowance of the application in view of the foregoing amendments and following remarks.

Applicant notes the guidelines for the preferred layout and content for patent applications. Since these are guidelines and not requirements, applicant elects not to use them at this time but will keep them in mind for use in future applications.

The Examiner's requirement for "New application papers with lines double spaced on good quality paper" is not understood. 37 CFR 1.52(b)(2)(i) specifically states that the application have "Lines that are 11/2 or double spaced". The lines of the instant specification are 11/2 spaced except for the first two lines of page one where the continuing data was inserted. Applicant is amending page 1 to correct the spacing for the continuing data. It is submitted the remainder of the specification meets the requirements of 37 CFR 1.52.

What does the Examiner mean by good quality paper? Applicant submits the application is in compliance with 37 CFR 1.52(a)(1). In fact, the undersigned has been using the instant paper when submitting applications to the PTO for the past nine years and has never had a problem. It is respectfully requested that the Examiner specifically point out why the application paper is unacceptable.

Applicant has amended the first full paragraph, i.e. lines 7-10, on page 3 to reflect that one of the documents referred to is not a patent document. It is submitted no new matter has been added by the amended paragraph. It is clear, e.g., from page 1, last paragraph, and page 2, line 26, that the compounds of the nonpatent document, i.e. European Journal of Pharmacology, 251, (1994), 1 were intended to be included for use in the instant invention.

As to incorporation by reference, the method of the invention covers all cGMP PDE 5 inhibitors and the cited documents are exemplifications of specific ones. Accordingly, incorporation by reference is not deemed necessary.

The rejection of claims 3 and 14 (subject matter of which is now in claims 23 and 27 respectively) under 35 USC 112, second paragraph, as being vague and indefinite is believed to have been overcome by the amendment to those claims . The patent and/or patent application numbers have been removed from both claims. In addition, the specific compounds from claim 4 have been added to claim 27.

The rejections of claims 5-7 and 12 and 13 under 35 USC 112, second paragraph, as being vague and indefinite have been mooted by the cancellation of those claims. Claim 11 has been rewritten as new claim 26. Claim 26 is submitted to meet the requirements of 35 USC 112, first and second paragraphs.

The rejection of claims 1-4 and 14 and 15 under 35 USC 102(e) as being anticipated by Sui et al. (USP 6,077,841) is respectfully traversed. Claims 1-4 have been cancelled and subject matter thereof included in new claims 21 – 24, respectively and claims 14 and 15 have been combined and rewritten as new claim 27.

The invention as presently claimed addresses the technical problem of administering cGMP PDE 5 inhibitors in an effective inhalable form. Specifically, the present invention is directed to a

method of treating sexual dysfunction which comprises administering by inhalation an effective amount of an inhibitor of cGMP PDE 5 in an atomisable composition or a finely divided particulate form to a subject in need of such treating. It is also directed to medicaments comprising specific cGMP PDE 5 inhibitors in an atomisable composition or a finely divided particulate form.

Sui et al. discloses specific PDE 5 inhibitors, i.e. certain substituted 5-heterocyclyl pyrazolopyrimidones, describing them as useful for treating erectile dysfunction. While Sui et al. mentions inhalation as one of a number of possible modes of administration (column 9, lines 58-64), there is no teaching or suggestion of how to administer the compounds in an effective inhalable form. Accordingly, it is submitted the instant invention is neither anticipated nor rendered obvious by Sui et al.

The rejection of claims 5-13 and 16-20 under 35 USC 103(a) as being unpatentable over Sui et al. in view of Purewal et al. (US 5,225,183) is respectfully traversed.

Sui et al. is discussed above.

Purewal et al. relates to medicinal aerosol formulations and names various propellants and suggests suitable particle sizes of certain finely divided solid powders.

According to *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 21 USPQ2d 1053 (CAFC 1991) relevant prior art for the purpose of determining non-obviousness is defined by the nature of the problem faced by the would-be inventor.

As mentioned above, the instantly claimed invention addresses the technical problem of administering cGMP PDE 5 inhibitors in an effective inhalable form. Purewal et al. is directed to providing an aerosol propellant system that does not contain chlorofluorocarbons, which are thought to react with the earth's ozone layer. Purewal et al. is silent as to cGMP PDE 5 inhibitors. It is submitted that one of ordinary skill in the art faced with applicant's problem of administering cGMP PDE 5 inhibitors in an effective inhalable form would not look to Purewal et al. for a solution to the problem.

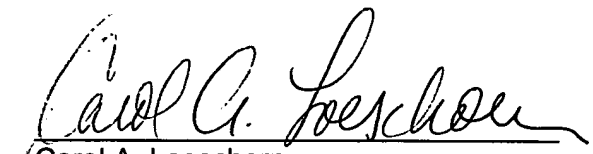
Indeed, combining the teaching of Sui et al. and Purewal et al. only becomes apparent when one knows applicant's problem and the claimed solution to that problem. The rejection is therefore based on a hindsight reconstruction of applicant's invention and as such cannot be reasonably or

fairly sustained. Accordingly, it is submitted that the instantly claimed invention is patentable over Sui et al. and Purewal et al. alone and in combination.

In view of the foregoing, reconsideration and allowance of the application is respectfully solicited.

Attached hereto is a marked-up version of the changes made to the specification by the current amendment. The attached page is captioned **"Version with Markings to Show Changes Made."**

Respectfully submitted,



Carol A. Loeschorn
Attorney for Applicant
Reg. No. 35,590

Novartis Corporation
Patent and Trademark Dept.
564 Morris Avenue
Summit, NJ 07901-1027
(908) 522-6932

Date: April 10, 2002

Encls.: Petition for Extension of Time in duplicate
Copy of IDS and Claim for Priority filed Sept. 18, 2001
Copy of Priority document
Copy of return postcard indicating receipt by PTO of IDS and Claim for Priority mailed Sept. 18, 2001

Version With Markings to Show Changes Made

In the Specification:

Page 1, the first paragraph has been amended as follows:

~~This is a continuation of International Application No. PCT/EP99/10250, filed December 21, 1999, the contents of which are incorporated by reference~~.

This is a continuation of International Application No. PCT/EP99/10250, filed December 21, 1999, the contents of which are incorporated by reference.

Page 3, paragraph beginning at line 7 has been amended as follows:

The invention includes, but is not limited to, the use of any compound within the scope of the ~~claims of the patent specifications~~ documents listed above, particularly the specific compounds disclosed ~~in those specifications~~ therein, more particularly the specific compounds disclosed in the Examples and, where the document is a patent, the claims of those ~~specifications~~ documents.